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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER				
LEITH, PATRICIA A				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/723,777

Applicant(s)

WAGONER, BRUCE KEVIN

Examiner

Patricia Leith

Art Unit

1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 September 2008.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 49-62 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 49-62 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/CDC)
4) ☐ Interview Summary (PTO-413)
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____
Paper No(s)/Mail Date _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/2/2008 has been entered.

Claims 49-62 are pending in the application and were examined on their merits.

Applicants' arguments pertaining to the previous rejection were persuasive and therefore, the previous rejections are hereby removed and thus arguments specifically pertaining to the previous rejections are subsequently rendered moot. However, new rejections are set forth, *infra*.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

Art Unit: 1655

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 49-53, 58 and 61 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The newly recited claims state the following limitations which cannot be found explicitly or implicitly in the original Disclosure as filed:

Claim 49:

'wherein urea and water in combination constitute greater than 50% by weight of the composition'

Claim 52:

'wherein the amount of sunflower oil in the composition is greater than the amount of shea butter'

Claim 58:

'wherein urea and water in combination constitute greater than 50% by weight of the composition'

Claim 61:

'the amount of sunflower oil in the composition is greater than the amount of shea butter'

Thus, these statements constitute **New Matter**. Applicant is asked to either point out in the original disclosure where these limitations can be found or to delete the New

matter in order to overcome this rejection. Because all claims depend either directly or indirectly from a claim which recites new matter, all of the pending claims are properly rejected under this statute.

Applicants' arguments were fully considered and found persuasive in-part.
Regarding the previous indication of new matter for the recitations of:

'from 20% to 50% of urea'

'from 2% to 15% of sunflower oil'

'0.5% to 10% of shea butter'

'urea in the composition is from about 20 to about 41%'

'from 1% to 4% of soybean sterol'

'wherein the amount of urea in the composition is from 20% to 50%'

'wherein the amount of sunflower oil in the composition is from 2% to 15%'

and 'wherein the amount of shea butter in the composition is from 0.5% to 10% by weight'

as being new matter, Applicants have successfully provided evidence from the specification to indicate that indeed Applicants contemplated the claimed ranges as set forth above.

However, with regard to 'wherein the amount of sunflower oil in the composition is greater than the amount of shea butter' and 'wherein urea and water in combination constitute greater than 50% by weight of the composition,' these arguments by Applicants' are not convincing to obviate this rejection for the following reasons:

First, the scope of the statement 'wherein the amount of sunflower oil in the composition is greater than the amount of shea butter' was not contemplated at the time the invention was made. Applicants, in traversal of the Office's opinion, rely on evidence from the specification which indicates that the highest percentage of sunflower oil in the composition is 15%, while the highest percentage of shea butter is only 10% (p. 9, Remarks). Applicants additionally point out that examples presented in [0055] as well as [0059] both use sunflower oil in a greater amount than the shea butter (p. 9, Remarks). While it is found correct that there are certain embodiments which disclose sunflower oil is used in a greater amount than shea butter, it is not seen where Applicants contemplated the importance of the use of sunflower oil in a greater amount than shea butter *in every instance* which is the breadth of 'wherein the amount of sunflower oil in the composition is greater than the amount of shea butter.' Thus, although it can be seen in claim 49 for example, where the upper limit for shea butter is 10%, and the upper limit of sunflower oil is 15%, and that the sunflower oil *could* be at a greater percentage at certain amounts, Applicants are now *requiring* that the amount of sunflower oil is *always greater than the amount of shea butter even considering that a large portion of the ranges overlap*. Contemplation of the large breadth of this

Art Unit: 1655

statement is not found in the instant specification as filed, and hence, it remains the opinion of the Office that the statement of 'wherein the amount of sunflower oil in the composition is greater than the amount of shea butter' is new matter.

Moving to the limitation in the claims which recites 'wherein urea and water in combination constitute greater than 50% by weight of the composition'; similarly, Applicants' arguments were not persuasive to overcome this rejection because it is not found in the instant specification as filed, where Applicants contemplated the importance of wherein urea and water are greater than 50% by weight of the composition. Applicants argue:

At the upper limit of urea concentration (50%), the additional presence of water in the formulation means that urea and water will necessarily constitute greater than 50% in the formulation. See also Tables 4 and 5 of the application, according to which the amount of urea and water is 79.1% and 76.7%, respectively. Accordingly, no new matter within the meaning of 35 U.S.C. § 132(a) has been introduced by the amendment of claims 49 and 58. (p. 5, Remarks)

However, again, while there are certain embodiments present in the original disclosure which indicate that the amount of water and urea combined will be present at greater than 50% of the composition', Applicants' recitation of 'wherein urea and water in combination constitute greater than 50% by weight of the composition' indicates that the combined amount of urea and water is *always* greater than 50% of the composition. Emphasis on this importance was not specified in the original disclosure and hence, it is deemed that the scope of 'wherein urea and water in combination constitute greater than 50% by weight of the composition' does not find support therein.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 45-52 are newly rejected under 35 U.S.C. 103(a) as being unpatentable over Durr et al. (US 5,997,889) in view of Gallina (US 5,529,987) in view of Glassman (US 2003/0212127 A1) in view of Guthauser (US 4,384,974) in view of Huard et al. (US 6,485,733 B1)

Durr et al. (US 5,997,889) taught a hand and body cream which advantageously comprised shea butter to improve the cream's moisturizing ability (see Abstract for example). Durr et al. further taught that water is added to the lotion/cream composition in order to vary the consistency. More specifically, Durr et al. taught:

Shea butter, also known as karite butter, is a yellowish or ivory-colored paste produced from the shea tree which grows wild in the savannah regions of West Africa. The paste is extracted from the almond-like fruit of the shea tree, and traditionally has been used by West Africans for treatment of skin and scalp ailments. **Shea butter has a high content of non-saponifiable fatty acids which make it an excellent moisturizer and skin conditioner.** In alternate embodiments of the hand and body creme composition, **shea butter is added in amounts of up to 8% by volume** of the total volume of the composition. The shea butter is used to modify the consistency of the

composition to a more fluid, lotion-like consistency while simultaneously adding skin moisturizing and skin conditioning benefits. Shea butter may be purchased from, for example, health food stores. In embodiments which use shea butter, it is incorporated into the composition by melting with the cocoa butter, Rosswax 2673, hydrogenated soybean flakes and beeswax.

In other embodiments, **water is added to vary the consistency of the hand and body creme composition and to accommodate the needs of those consumers with more oily skin. Increased amounts of water increase the fluidity of the composition. Water is added in an amount of up to 5% by volume of the total volume of product.** In one embodiment, distilled water is used, but bottled water or commonly available tap water may be used. In embodiments which include water, the water is added and blended in when the oil mixture and hot wax mixture are added together and blended. (col. 4, lines 5-34, emphasis added)

Durr et al. did not propose the incorporation of sunflower oil or urea into their composition.

Gallina (US 5,529,987) discloses a topical composition comprising hyaluronic acid and urea (see Abstract). Describing urea in their topical formulations, Gallina states the following:

Urea is a product of protein metabolism and is the chief nitrogenous constituent of human urine. **Urea is a protein denaturant that promotes hydration of keratin and mild keratolysis in dry and hyperkeratotic skin. It is used topically in the treatment of psoriasis, ichthyosis, atopic dermatitis and dry scaly conditions, usually in a 2% to 25% cream or lotion.** Urea has long been used as an osmotic diuretic, to promote the healing of infected wounds, and for its antiseptic value. (col. 2, lines 22-30, emphasis added)

Glassman (US 2003/0212127 A1) disclosed a method for treating actinic keratosis via pre-treatment with urea (see entire reference, especially Abstract and [0014]). Glassman et al. specifically taught:

The invention provides methods using urea for the treatment of actinic keratosis, which includes a pre-treatment with about 10 to about 60 wt-%, about 21 to about 40 wt-%, or about 40 wt-% urea. Pretreatment with urea may assist an individual administering therapy in viewing an AK to be treated. For example, pre-treatment with urea, a keratolytic and softening agent, may expose hidden or non-visible AK by removing scaly, dry skin as well as softening tough

skin. ([0014])

Amongst other conventional lotion/cream additives, it is noted that Glassman specifically suggested the incorporation of antioxidants such as butylated hydroxytoluene (see [0052]).

Guthauser (US 4,384,974) discloses a water-in-oil emulsions for topical cosmetics (see Abstract). Ingredients of Guthauser's emulsions included water and, in the case of a heavy lotion "with emphases on moisturizing and emollient properties" Guthauser proposes the use of oils such as sunflower oil (see entire reference, especially columns 1 and 2, and more especially col. 2, lines 39-45). Guthauser clearly shows that the oils in the composition can be varied (see Examples I-X (col's 3-4) and the specific disclosure of wherein the oil is present between 10 and 20% (see claim 1 for example).

Known, conventional cosmetic cream additives are routinely admixed to provide varying degrees of skin moisturization as well as varying consistencies (e.g., cream -vs- lotions). Huard et al. (US 6,485,733 B1) for example, disclosed that the ingredients of VaselineTM Intensive Care Extra Strength Lotion included, *inter alia*, sunflower seed oil, soya sterol, glyceryl stearate, stearic acid, triethanolamine, glycerine, water, lecithin, tocopherol acetate, retinyl palmitate, disodium EDTA and urea (see col. 18, lines 51-63). All of the claimed ingredients were known cosmetic cream/lotion additives and

Huard et al. provides further evidence that these ingredients are commonly admixed together to manufacture moisturizing skin creams.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit since each is well known in the art for lending moisture protection to the skin or for being used in cosmetic creams/lotions to hydrolyze and moisturize skin. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman*, 1943 C.D. 518. Accordingly, the instant claims, in the range of proportions where no unexpected results are observed, would have been obvious to one of ordinary skill having the above cited references before him, especially considering that the prior art already taught each claimed ingredient to be used in ranges which overlap with the ranges present in the claims.

"Reading a list and selecting a known compound to meet known requirements is no more ingenious than selecting the last piece to put in the last opening in a jig-saw puzzle." 325 U.S. at 335, 65 USPQ at 301. The selection of the claimed ingredients for use in topically-applied skin cream for treating dry skin is considered obvious and well within the purview of the ordinary artisan at the time the invention was made.

Further, while the prior art did not specifically teach that the amount of urea and water was greater than 50% by weight of the composition or wherein 'the amount of sunflower oil in the composition is greater than the amount of shea butter', it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233; 235 (CCPA 1955). see MPEP § 2144.05 part II A. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal concentrations of all of the claimed components, including urea and water because these ingredients were art-recognized result-effective variables which would have been routinely determined and optimized in the pharmaceutical art. Further, while the prior art taught that urea was usually used in cosmetic creams up to 50% of the composition, Glassman clearly teaches that the use of a topical composition comprising up to 60% of urea for skin softening. The teachings of Glassman thus render 'wherein urea and water in combination constitute greater than 50% of the composition' obvious because if one used urea in a cosmetic composition for skin softening the ordinary artisan would have recognized that creating a cream having 60% urea as a softening agent was predictable in view of Glassman. With regard to wherein the claims state wherein 'the amount of sunflower oil in the composition is greater than the amount of shea butter' is made obvious by the combination of references; Durr taught that shea butter was advantageously used up to 8% and Guthauser taught that sunflower oil could be used in their moisturizing cream from 10-20%. Given this information, the ordinary artisan

would have recognized that the sunflower oil could have been added into a topically-applied cosmetic cream for softening skin which contained more sunflower oil than shea butter. It would be conventional and within the skill of the art to identify the optional concentrations of a given conventional cosmetic additive to create stabilized, pH balanced skin softening cosmetic creams. Such optimization is deemed an obvious means for modifying the flowability and moisturization properties of a cosmetic cream/lotion.

Claims 45-53 are newly rejected under 35 U.S.C. 103(a) as being unpatentable over Durr et al. (US 5,997,889) in view of Gallina (US 5,529,987) in view of Glassman (US 2003/0212127 A1) in view of Guthauser (US 4,384,974) in view of Huard et al. (US 6,485,733 B1) in view of Znalden et al. (US 5,595,745) in light of Wikipedia (accessed 11/11/2008)*.

The teachings of Durr et al., Gallina, Glassman, Huard et al. and Guthauser were discussed *supra*. While Huard et al. did teach that the Vaseline product contained soy sterol, they did not specifically teach the purpose for its inclusion.

According to Znalden et al. (US 5,595,745), soy sterol was advantageously used as an emollient in their topically-applied petroleum butter composition for moisturization and skin healing (see entire reference, especially the Abstract and col. 2, lines 35-45). Znalden et al. recommended the use from 0.5 to 20%, 1 to 10% or more preferably, from 2-8% of the emollient by weight of the composition (col. 2, lines 26-34).

According to Wikipedia, "Emollients are substances that soften and soothe the skin. They are used to correct dryness and scaling of the skin. They are a key component in the manufacture of lipstick, lotions, and other cosmetic products" (see one page print-out from Wikipedia.org)*.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit since each is well known in the art for lending moisture protection to the skin or for being used in cosmetic creams/lotions to hydrolyze and moisturize skin. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman*, 1943 C.D. 518. Accordingly, the instant claims, in the range of proportions where no unexpected results are observed, would have been obvious to one of ordinary skill having the above cited references before him, especially considering that the prior art already taught each claimed ingredient to be used in ranges which overlap with the ranges present in the claims.

Further, while the prior art did not specifically teach that the amount of urea and water was greater than 50% by weight of the composition or wherein 'the amount of sunflower oil in the composition is greater than the amount of shea butter', it has been

held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233; 235 (CCPA 1955). see MPEP § 2144.05 part II A. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal concentrations of all of the claimed components, including urea and water because these ingredients were art-recognized result-effective variables which would have been routinely determined and optimized in the pharmaceutical art. Further, the while the prior art taught that urea was usually used in cosmetic creams up to 50% of the composition, Glassman clearly teaches that the use of a topical composition comprising up to 60% of urea for skin softening. The teachings of Glassman thus render 'wherein urea and water in combination constitute greater than 50% of the composition' obvious because if one used urea in a cosmetic composition for skin softening the ordinary artisan would have recognized that creating a cream having 60% urea as a softening agent was predictable in view of Glassman. With regard to wherein the claims state wherein 'the amount of sunflower oil in the composition is greater than the amount of shea butter' is made obvious by the combination of references; Durr taught that shea butter was advantageously used up to 8% and Guthausen taught that sunflower oil could be used in their moisturizing cream from 10-20%. Given this information, the ordinary artisan would have recognized that the sunflower oil could have been added into a topically-applied cosmetic cream for softening skin which contained more sunflower oil than shea butter. It would be conventional and within the skill of the art to identify the optional

concentrations of a given conventional cosmetic additive to create stabilized, pH balanced skin softening cosmetic creams. Such optimization is deemed an obvious means for modifying the flowability and moisturization properties of a cosmetic cream/lotion.

Claims 49-62 are newly rejected under 35 U.S.C. 103(a) as being unpatentable over Durr et al. (US 5,997,889) in view of Gallina (US 5,529,987) in view of Glassman (US 2003/0212127 A1) in view of Guthauser (US 4,384,974) in view of Huard et al. (US 6,485,733 B1) in view of Znalden et al. (US 5,595,745) in light of Wikipedia (accessed 11/11/2008)* in view of Garrison et al. (US 5,569,651) in view of Hill et al. (US 4,233,295) in view of McNulty et al. (US 2005/0048105 A1) in view of Barker (US 4,335,103).

The teachings of Durr et al., Gallina, Glassman, Guthauser, Huard et al. and Znalden et al. were discussed *supra*. While Glassman suggested the incorporation of butylated hydroxytoluene into their cosmetic composition, Hill et al. provides additional conventional knowledge that antioxidants such as butylated hydroxytoluene preserved cosmetics such as creams and lotions and hence provide the advantage for adding this ingredient (see teachings below which have been used in previous Office actions). None of these references specifically taught the inclusion of disodium EDTA or sodium polyacrylate (sodium PCA).

Hill et al. (US 4,233,295) teaches that butylated hydroxytoluene, an antioxidant, is advantageous to incorporate into creams, lotions or ointments in order to preserve the active ingredients therein (see col. 6, lines 23-26).

McNulty et al. (US 2005/0048105 A1) teaches that sodium polyacrylate is a known thickening agent for creams and lotions[0069].

As explained by Garrison et al. Garrison et al. use disodium EDTA in their anti-acne composition and explain that "...disodium EDTA acts as a chelator to sequester any discoloration causing metal ions" (see entire reference, especially the Abstract and col. 3, line 65- col. 4, line 9) In this same paragraph of Garrison et al., they teach that triethanolamine is a suitable pH adjuster. Barker et al., which teachings follow, explain more about the role of triethanolamine in cosmetic compositions.

Barker et al. (US 4,335,103) disclose a multiphase cosmetic cream composition comprising triethanolamine, which as explained by Barker et al., neutralizes the pH of the thickening agents in the cosmetic composition (see entire reference especially col. 5 lines 37-50).

One of ordinary skill in the art would have been motivated to combine the instantly claimed ingredients into a topical cream/lotion for moisturizing the skin because each claimed ingredient is a known, conventional additive in the art of

cosmetic creams and lotions. The ordinary artisan would have had a reasonable expectation of success in producing the claimed composition since each claimed ingredient was well-known in the art for lending moisture protection to the skin or for being used to stabilize/thicken topical cosmetic lotions/creams. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman*, 1943 C.D. 518. "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted) (Claims to a process of preparing a spray-dried detergent by mixing together two conventional spray-dried detergents were held to be *prima facie* obvious.).

While claim 54 states 'consisting of', it is deemed that this claim is obvious because the ordinary artisan would have found the combination of claimed elements predictable in that each element is known in the art as a conventional cosmetic cream additive. There is nothing new in the claim which has not previously been used as a conventional cosmetic cream additive, and the specification provides no evidence of an unexpected result of the combination of claimed elements over what would be predictably expected of such a combination. Accordingly, the instant claims, in the

range of proportions where no unexpected results are observed, would have been obvious to one of ordinary skill having the above cited references before him.

Further, while the prior art did not specifically teach that the amount of urea and water was greater than 50% by weight of the composition or wherein 'the amount of sunflower oil in the composition is greater than the amount of shea butter', it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233; 235 (CCPA 1955). see MPEP § 2144.05 part II A. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal concentrations of all of the claimed components, including urea and water because these ingredients were art-recognized result-effective variables which would have been routinely determined and optimized in the pharmaceutical art. Further, the while the prior art taught that urea was usually used in cosmetic creams up to 50% of the composition, Glassman clearly teaches that the use of a topical composition comprising up to 60% of urea for skin softening. The teachings of Glassman thus render 'wherein urea and water in combination constitute greater than 50% of the composition' obvious because if one used urea in a cosmetic composition for skin softening the ordinary artisan would have recognized that creating a cream having 60% urea as a softening agent was predictable in view of Glassman. With regard to wherein the claims state wherein 'the amount of sunflower oil in the composition is greater than the amount of shea butter' is made

obvious by the combination of references; Durr taught that shea butter was advantageously used up to 8% and Guthauser taught that sunflower oil could be used in their moisturizing cream from 10-20%. Given this information, the ordinary artisan would have recognized that the sunflower oil could have been added into a topically-applied cosmetic cream for softening skin which contained more sunflower oil than shea butter. It would be conventional and within the skill of the art to identify the optional concentrations of a given conventional cosmetic additive to create stabilized, pH balanced skin softening cosmetic creams. Such optimization is deemed an obvious means for modifying the flowability and moisturization properties of a cosmetic cream/lotion.

The Supreme court has acknowledged that:

When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. **If a person of ordinary skill can implement a predictable variation..103 likely bars its patentability...**if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond that person's skill. A court must ask whether the improvement is more than the predictable use of prior-art elements according to their established functions...

...the combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results (see *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 U.S. 2007) emphasis added.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of

ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

It is noted that amending claim 54 to include specific amounts (or ranges) of each ingredient may be allowable.

*This reference is used to relay an inherent property of an emollient and is not used in the basis for rejection *per se*.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached on Monday - Friday 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Patricia Leith
Primary Examiner
Art Unit 1655

/Patricia Leith/
Primary Examiner, Art Unit 1655
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